JONES DAY

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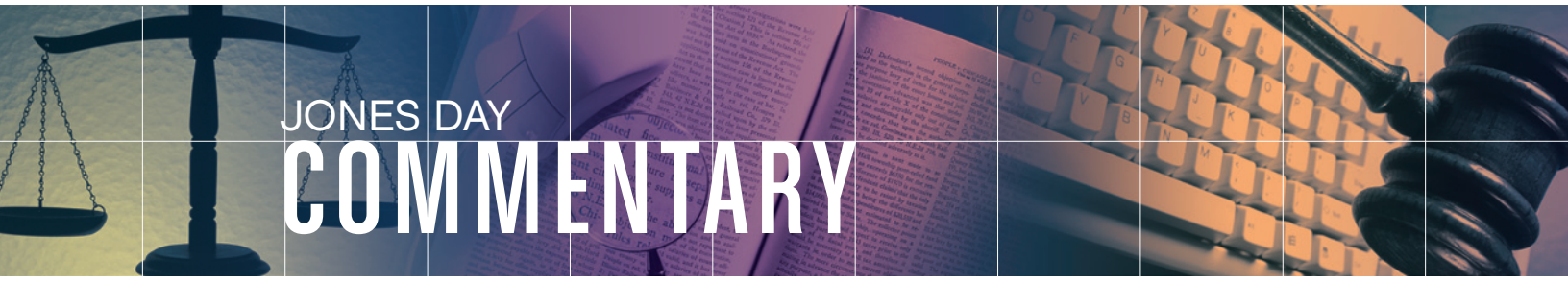

IS YOUR SMART PHONE AN FDA-REGULATED MEDICAL DEVICE?

FDA announces plans to regulate "Mobile Medical Applications"

An enormous number of software applications have been developed for use on handheld computers such as smart phones, tablet computers, and personal digital assistants. Some of these applications are marketed as suitable for diagnosing or treating disease, or for controlling other machines that are used for these purposes.

On July 21, 2011, the U.S. Food and Drug Administration issued a "draft guidance" discussing how it intends to regulate "mobile medical apps."[1] The FDA views handheld computers loaded with these apps to be medical "devices" subject to extensive FDA regulation. The FDA's draft guidance sets out its current thinking regarding when apps will trigger regulatory oversight, and how the FDA intends to enforce its regulations.

Since the FDA will be exercising its authority over industries that may be unaccustomed to FDA regulation, the affected companies are in danger of inadvertent regulatory violations. The FDA is focusing primarily on companies that write or design software for medical apps. But, depending on the circumstances, companies that manufacture or distribute the hardware also face regulatory risk. All companies in any way involved with handheld computers or their apps would be well advised to consult with regulatory counsel to determine how they may be affected by the FDA's device regulations.

The FDA is actively seeking input into its policies. Companies that want a say in the FDA's enforcement practices should promptly submit comments to the new "draft guidance."

1 Draft Guidance for Industry and Food and Drug Administration Staff; *Mobile Medical Applications*.

MEDICAL DEVICES AND THE FDA

The FDA has long had authority to regulate medical "devices," a term that encompasses instruments, machines, implants, and other articles "intended for use in the diagnosis of disease ... or in the cure, mitigation, treatment, or prevention of disease ...." FD&C Act, § 201(h). Regulated "devices" range from extremely simple items, such as dental floss and stethoscopes,[2] to pacemakers[3] and highly sophisticated medical equipment.

Manufacturers and others involved in the marketing of medical devices are subject to a raft of regulatory requirements. *See generally* 21 C.F.R. Chapter 1, Subchapter H. Many devices cannot be marketed without prior permission from the FDA. FD&C Act, § 510(k); 21 C.F.R. § 807.100(a). Novel or potentially dangerous devices may be subject to a rigorous premarket approval process requiring expensive and time-consuming clinical trials. *See* FD&C Act, § 515; 21 C.F.R. Part 814.

Other regulations mandate registering manufacturing establishments, ensuring proper labeling, reporting adverse events, malfunctions, and corrections, and (depending on the device at issue) manufacturing in accordance with "quality system" and "current good manufacturing process" regulations, tracking the devices after they are sold, and performing postmarket surveillance to collect data on the device's safety and efficacy.[4]

MOBILE MEDICAL APPS

The popularity of smart phones and other handheld computers has resulted in a profusion of software applications designed to run on the handheld computers. Some of these "apps" are designed for medical purposes. The FDA's recent draft guidance lists 34 types of apps that the FDA views as "mobile medical apps," including apps that permit the user to analyze medical data, screen patients for blood transfusions, control other medical devices, etc. According to the new draft guidance, a handheld computer loaded with such apps is a "device," as that word is used in the Food, Drug, and Cosmetics Act, and is therefore subject to the full range of device regulations.

Medical apps are growing in popularity. According to *The New York Times*, one smart phone app, "Epocrates," is used by "nearly half of the nation's doctors" to "look up information on drug dosing, interactions and insurance coverage while seeing a patient."[5] Multiple websites are devoted to reviewing and discussing medical apps, including one site that claims "400,000 views a month by the medical community." www.iMedicalApps.com

The FDA does not view all applications with medical purposes as requiring regulatory supervision. The FDA intends to "exercise its discretion to decline to pursue enforcement actions" in connection with some classes of medical applications. Applications that will not be the subject of enforcement actions include electronic versions of medical reference works, apps relating to "maintaining general health and wellness," and apps used to perform general office functions (tailored to a medical office or otherwise). The boundary line appears to reflect whether the app is marketed for a "specific medical indication," or to analyze a specific patient.

However, the FDA's stated intent to forebear will be of little comfort should the FDA change its mind. The guidance document is merely a draft. Furthermore, even a final guidance document will not excuse anyone from complying with all applicable regulations and will not bind the FDA. Therefore, all companies involved with medical mobile apps should carefully analyze whether they are selling a regulated "device."

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2 21 C.F.R. § 872.6390 (dental floss); § 870.1875 (stethoscopes).
3 21 C.F.R. § 870.3610.
4 *See* 21 C.F.R. Parts 801, 803, 806, 807, 814, 820, 821, 822.
5 New York Times, *Drug App Comes Free, Ads Included* (July 28, 2011).

WHEN IS A HANDHELD COMPUTER A "DEVICE"?

When determining whether a machine is a regulated "device," the question is not whether the machine *can* be used for specified medical purposes, but whether the machine is "intended for" such uses. *See* FD&C Act, § 201(h). As applied to handheld computers, this definition results in considerable ambiguity. Some purchasers will want to use handheld computers to diagnose or treat disease, and some sellers will actively market this ability. But most consumers will not seek out medical apps, and even a medical professional is likely to use a handheld computer primarily for non-medical purposes.

The FDA's draft guidance indicates that the status of a machine is not defined by its attributes, but by the intent of the seller. The determination of the seller's intent will often (but not always) turn on the seller's marketing claims and the accompanying labeling. For example, the draft guidance indicates that a machine will be viewed as a "device" if advertised as capable of performing medical functions. The same machine might not be a regulated device if sold without such claims. Thus sellers of handheld computers and mobile apps have some ability to control whether they are selling regulated "devices." However, a seller's intent can also be "shown by the circumstances surrounding the distribution of the article." 21 C.F.R. § 801.4 (defining "intended uses" in connection with labeling obligations). It is therefore unclear whether a seller of a handheld computer can achieve a safe harbor merely by avoiding making medical claims in its advertising and labeling.

Adding to the complexity is the fact that different actors in the supply chain may have different intentions. As a result, the FDA indicated that a machine that is not a "device" when first sold might become a regulated device if then resold—even if unchanged—by a distributor who markets the machine's potential use to aid in medical diagnosis or treatment.

WHO IS THE "MANUFACTURER" OF A MOBILE MEDICAL APP?

Manufacturers, as a practical matter, usually bear primary or exclusive responsibility for compliance with the full range of applicable regulations. The question of who is the "manufacturer" of a device thus bears real-world significance, and is addressed in the FDA's new draft guidance.

At present, the FDA is most focused upon those who create and control the software. Thus the primary manufacturers, at least under the FDA's current view, are the software designers and programmers. These "manufacturers" include the companies that develop the specifications for the apps and contract with others to perform the programming. Some medical apps operate by granting access to a web site that provides the application's functionality. For these apps, the "manufacturers" include the company responsible for the web site.

By contrast, the FDA does not appear to be focused upon the hardware involved (*i.e.,* the handheld computer). A company that merely manufactures the hardware platform—without intending that it be used as (or as part of) a medical device—is currently considered by the FDA to be a mere "component manufacturer." Component manufacturers are exempt from many device regulations, including the requirements relating to registering manufacturing facilities, listing the medical devices produced, filing premarket notifications or approval applications, and observing "good manufacturing practices." 21 C.F.R. §§ 807.65(a), 807.81(a), 820.1(a).

Similarly, the draft guidance indicates that companies that solely perform a distribution function (such as enabling online sales of apps) are not manufacturers.

Manufacturers, however, are not the only companies that have regulatory burdens relating to medical devices. Importers often have the same duties as manufacturers.[6] Even distributors must maintain incident reports and make them available to FDA inspectors upon request. 21 C.F.R. § 803.18(d)(1)-(3).

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6 *See* 21 C.F.R.§§ 803.40 (adverse events reporting); 806.10(a) (reports of corrections and removals); 807.20(a)(4) (registration of manufacturing establishments); 807.81 (premarket notification); 821.4 (tracking devices after sale); 822.3(g) (postmarket surveillance).

THE FDA IS SOLICITING COMMENTS

FDA policy regarding software-driven medical devices has been in flux for some time. An earlier attempt at a single, overarching software policy was withdrawn as a failure in light of fast technological developments and dramatic increases in the number of software-driven devices. *See* 70 F.R. 824 (Jan. 5, 2005) (withdrawing "Draft Software Policy"). Given this history, and given the FDA's awareness that it is regulating a rapidly changing industry, the FDA should be receptive to comments on the new draft guidance.

Accordingly, the FDA is soliciting comments regarding its Medical Mobile Apps draft guidance. Such comments can help inform the FDA regarding who should bear the burdens connected with the device regulations, and how the burdens can be minimized.

Comments are due by October 19, 2011. 76 F.R. 43689 (July 21, 2011).

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